U.S. COMPETITIVEERS

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The Contractor agrees that any products embodying any waived invention or produced through the use of any weived invention will be manufactured substantially in the United States, unless the Contractor can show to the smisfection of DOE that it is not communically feasible to do so. In the event DOE agrees to foreign manufacture, there will be a requirement that the Government's amount of the technology be recognized in some appropriate manuar, e.g., recomparent of the Government's investment, etc. The Commetter further agrees to make the above condition binding on any assignce or licenses or any entity otherwise acquiring rights to any waived invention including subsequent assignees or licensees. Should the Contractor or other such entity receiving rights in any weived invention undergo a change in ownership amounting to a controlling interest, then the waiver, assignment, license, or other transfer of rights in any waived invention is suspended until approved in writing by DOE.

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Statement of Considerations

Class Waiver to Non-Bayh-Dole entities of the Government's U.S. and Foreign Patent Rights in Inventions made in the course of or under arrangements entered into under the Department of Energy's Nuclear Energy Research Initiative (NERI) Program DOE WAIVER NO. W(C)-99-007, (SAN-681)

In January 1997, the President requested his Committee of Advisors on Science and Technology (PCAST) to review the current national energy research and development (R&D) portfolio and provide a strategy to insure that the U.S. had a program to address the nation's energy and environmental needs for the next century. In its November 1997 report responding to this request, the PCAST Energy Research and Development Panel determined that assuring a viable nuclear energy option to help meet our future energy needs is important and that a properly focused R&D effort should be implemented by the Department of Energy (DOE) to address the principal obstacles necessary to achieve this goal. These obstacles include issues involving nuclear waste, proliferation, economics, and safety. In response to these recommendations, the DOE proposed the Nuclear Energy Research Initiative (NERI), composed of projects selected from individual or collaborative applications from universities, the DOE national laboratories, industry, and non-profit organizations.

DOE received funding under the Energy and Water Development Appropriation Act of 1999, Public Law 105-245, which stipulated that the NERI Program should provide up to \$19M to universities, private industry, and the national laboratories for the purpose of conducting basic science research and development in the fields of new nuclear reactor design, advanced fuel design, proliferation resistance, treatment and storage of nuclear waste, and other related areas such as materials and computational science. A solicitation, DE-PS03-99SF21764, announcing the NERI assistance program was published in the Federal Register by DOE's Office of Nuclear Energy, Science and Technology on Nov. 6, 1998. Applications were evaluated in accordance with the Merit Review System as required by 10 CFR Part 600. Awards were based upon the published technical and business evaluation criteria.

Except in cases where an existing DOE Laboratory Management and Operating (M&O) contractor is serving either as the lead organization or principal collaborator on a particular project, in which case interoffice work orders are issued, the NERI Program generally consists of DOE-OAK managed financial assistance awards. As currently being implemented, the work orders, grant awards, cooperative agreements, and/or subcontracts which may be issued thereunder, span all of the NERI research and development activity areas. Although the overall Program is authorized through the year 2002, NERI is currently funded only through fiscal year 2000, so all of the current financial assistance awards contain options for two subsequent one year renewal periods.

Where the cooperative agreement recipient or any grant awardee is a small business or nonprofit organization receiving funds under this Program, Public Law 96-517 as amended, entitles such party, with certain exceptions, to have election rights to subject inventions pursuant to the terms of that law as implemented by DOE regulations at 48 CFR 952.227-11. Thus, small business entities and nonprofit organizations already have a statutory right to elect to file on any of their inventions made in the course of any funding agreement which they enter into under the NERI Program. However, where the respective party is not a small business or non-profit organization, section 152 of the Atomic Energy Act of 1954, as amended (42 USC 2182), and Section 9 of the Federal Non-nuclear Energy Research and Development Act of 1974 (42 USC 5908), generally require that the Government take title to subject inventions unless a waiver is granted.

It is the purpose of this class waiver to provide for a waiver of the Government's patent rights under the authority of the aforementioned 42 USC 2182 and 5908, in accordance with DOE's patent waiver regulations at 10 CFR 784.7. Most other federal agencies are not subject to DOE-like Government patent ownership statutes. These agencies are generally in a position to have large business participants obtain invention rights in a manner like small business or non-profits pursuant to the Presidential Memorandum of 2/18/83, as modified by Executive Order 12591. Grant of this waiver would serve to place all of NERI collaborators in approximately similar circumstances regarding the procedural requirements for invention ownership. 10 CFR 784.7 states that "Class waivers may be appropriate in situations where all members of a particular class would likely qualify for an advance or identified invention waiver." The authorization for class waivers is specifically found at 42 USC 5908 (c).

In particular, the scope of this class waiver is directed to subject inventions of large business cooperative agreement recipients, grant awardees, and/or subcontractors which may receive funding thereunder, as the case may be, (hereinafter "participants") collaborating in the NERI program. It is DOE's intent that, as a result of this class waiver, NERI participants which sign any particular agreements containing the clause at 48 CFR 952.227-13 be able to initially retain the patent rights to their respective subject inventions. This waiver is subject to the DOE's retention of a royalty-free, non-transferrable, irrevocable, nonexclusive license to practice any subject invention by or on behalf of the U.S. Government anywhere in the world, march-in rights and a U.S. preference provision comparable to those set forth in 35 U.S.C. 202 and 204. It is expected, and is a condition of this class waiver, that a large business participant which assigns principal ownership or exclusive license rights in a subject invention will provide for retention by the Government of these rights in any such instrument conveying substantial ownership to a third party.

A class waiver of the scope described hereinabove would promote the commercial utilization of inventions arising from the NERI program by facilitating transfer of invention rights from the Government to the interested private sector participants, thereby making the benefits of the NERI program widely available to the public in the shortest practicable time. This class (advance) waiver in addition serves to encourage private participation in the NERI program by providing assurance that statutory Government ownership of inventions would not inhibit commercialization plans. Thus, statutory objectives of DOE's patent waiver policy are being met.

Regarding statutory patent waiver considerations, since a major purpose of the NERI Program is to promote basic science research and development in the field of applied nuclear technology, grant of this class waiver should serve to foster the intended commercial use of the results of the Program by leaving invention rights with the private sector. Since the NERI Program involves large business participants which generally have worked in the nuclear energy field for 25 years or more, they have invested many millions of their own internal funds developing similar technology in the past. Many of these large businesses have numerous publications, a portfolio of background patents, and technical expertise to their credit, not be mention vast facilities that have been constructed with state-of-the art equipment. NERI generally involves projects closely or directly related to technology previously developed at private expense and on which there is, or is expected to be, a private commercial position held by participants. Hence, DOE's statutory waiver considerations are being substantially met.

Grant of this class waiver should not result in adverse effects on competition or market concentration since the NERI Program is directed to a multiplicity of projects, each of which is generally directed to advancing the state of nuclear technology with the objective of maintaining a competitive position in overseas markets and a future domestic market. In many cases, joint inventions or cross license rights may be dispersed among teams of collaborating parties, or be retained by one firm with a unique interest in developing a particular technology to the point of commercialization. Although the success of this NERI Program may significantly alter the economics of the nuclear energy industry in the long term, e.g. after ten years, it is likely that a five year period of time is necessary before these new technology concepts can be proven in the field. Hence, this waiver is viewed as having a limited effect on competition, especially in the near term. On balance, invention rights disposition fostered by this class waiver should serve to enhance competition by encouraging development of new or improved technologies, rather than serving to concentrate markets.

Accordingly, in view of the statutory purposes of DOE waiver policy, and the objectives for the Nuclear Energy Research Initiative, and in view of the factors to be considered under DOE's statutory patent waiver policy, all of which have been considered, it is recommended that this class waiver as set forth above will best serve the interest of the United States and the general public. It is therefore recommended that the waiver be granted.

Thomas O'Dwyer, Patent Attorney Intellectual Property Law Division DOE, Oakland Operations Office Based on the forgoing Statement of Considerations, it is determined that the interest of the United States and the general public will best be served by waiver of United States and foreign patent rights, and therefore the waiver is granted. This waiver shall not affect any patent wavier previously granted.

CONCURRENCE



Madeline A. Feltus, Associate Director Office of Technology Office of Nuclear Energy, Science and Technology Paul Gottlieb, Assistant General Counsel for Technology Transfer and Intellectual Property